

MATURE MINOR INFORMATION SHEET

Perth Children´s Hospital

**The effect of different exercise intensities in improving glycaemic control in individuals with impaired hypoglycaemia awareness**

**Why are we asking you?**

We are asking you to take part in this study because you have type 1 diabetes, are aged between 14 and 18 years, and have reduced awareness of your hypoglycaemia.

**Why are we doing the study?**

Usually people with type 1 diabetes (T1D) know when they are going low by showing signs like becoming pale and shaky. This is called hypoglycaemia awareness. Some people with T1D though are not able to feel their hypoglycaemia signs and so they may be at a higher risk of having a severe hypo. Avoiding hypos for several weeks can improve hypoglycaemia awareness in these people, but this often means keeping blood glucose levels quite high for a while which is not an ideal solution.

Exercise is helpful for people with diabetes in improving fitness, bone health, and wellbeing, and has also been found to be useful in improving glucose levels. This study is investigating the effect of two different exercise programs on their glucose levels and overall glucose control.

**What will the study tell us?**

We want to see if a 4-week program of exercise (either low-intensity or high-intensity cycling) at home is achievable, if it improves hypoglycaemia awareness, time spent in target range (3.9 to 10 mmol/L) and reduces hypoglycaemia in people with T1D.

**Who is carrying out the study?**

The study is being carried out by Dr Mary Abraham and Professor Tim Jones, together with the Research Team at Perth Children´s Hospital and Telethon Kids Institute.

**Do you have to take part?**

No, you do not have to take part in this study. If you decide to take part and then later change your mind, that is ok. You can pull out at any time and it will not change the way you are treated by your clinic team.

**What will I be asked to do if I decide to take part in this study?**

If you are interested, please read the information below before you decide whether or not you would like to participate.

**Study outline:**

This study involves a screening visit followed by 8 study visits over 20 weeks. These visits are described below.

**Screening visit: Phone, Face to Face or Email:**

A member of the research team will check to determine that you meet the inclusion criteria for this study. You will also be asked to complete a hypoglycaemia awareness questionnaire to make sure you are eligible for the study.

**Week 1: Face-to-face familiarisation session:**

The first visit will be a familiarisation visit, where you will meet the study team in the research facility. At this visit you can ask any questions about the study to make sure that you know exactly what is involved and you are happy to participate. If you agree to take part, we will ask you to sign a consent form. We will then collect some baseline details about your diabetes, physical activity, ask you to complete another hypoglycaemia awareness questionnaire, and show you the exercise bike that will be used for the study. You will also be asked to sprint on this exercise bike as hard as you can for 10 seconds. This will allow us to figure out how hard you should exercise for your exercise sessions at home. If you are not already on a continuous glucose monitoring system (CGMS), you will be provided with a Dexcom G5 CGMS to use during the study period. This system will monitor your tissue glucose levels and provide you with glucose readings every 5 minutes which will be available real-time on your phone. You will receive education about how to insert and use it from a certified diabetes educator. Lastly, you will be provided with a hypoglycaemia symptom diary to record your hypoglycaemia, hypoglycaemic symptoms and treatments over the next two weeks.

**Week 3:** **Home-visit, set-up of ergometer at home, randomisation:**

We will visit you at home to help set up the same exercise bike from Week 1, and also provide you with an activity-monitoring watch (Garmin Forerunner) which will also measure your heart rate. You will be trained by a member of the research team on the use of the exercise bike, and we will help you with the setup and use of the activity monitoring watch which will allow the research team to view your completed exercise sessions through Garmin’s online platform (Garmin Connect).

You will then be randomly assigned to complete *low-intensity* exercise or *high-intensity* exercise 3 times a week for 4 weeks. The exercise sessions should be done at the same time of the day during the study, either in the morning before breakfast, or at least 3 hours after your last insulin bolus (before your evening meal) as below:

*Low-intensity exercise:* Continuous cycling for 16 minutes at 5% of your peak power output achieved at the Week 1 session.

*High-intensity exercise:* 2 minutes of cycling at 5% of your peak power output, followed by four 15-second maximal sprint efforts each separated by 4 minutes of cycling at 5% of your peak power, and finishing with 2 minutes of cycling at 5% of your peak power (16 minutes total).

The visiting researcher will assist in helping you become familiar with both exercise formats, and the activity-monitoring watch will be programmed to alert you when you need to start and stop with the repeated sprints. You will also be advised to eat a meal rich in carbohydrates and proteins following exercise (for example, spaghetti bolognese).

We will also collect your hypoglycaemia symptom diary from week 1, and provide you with a new hypoglycaemia symptom diary which you will be asked to complete from week 5 to week 7.

**Week 5:** **Phone call to commence record of symptom diary**

We will contact you to remind you to begin recording your hypoglycaemic events over the next two weeks in your symptom diary.

**Week 7:** **Face-to-face hospital or home visit, and end of first exercise program**

You will be asked to complete questionnaires on hypoglycaemia awareness and on your enjoyment of physical activity, and return your hypoglycaemia symptom diary. If you were randomised to the high-intensity exercise program, you will be asked to complete a short semi-structured interview with one of our research team, which we will record with your permission, so we can see how achievable the exercise program was. We will also collect your symptom diary, and provide you with a new symptom diary and new continuous glucose sensors. This visit also marks the start of the 8-week washout or ‘break’ period from any study-related exercise.

**Week 13: Phone** **call to commence record of symptom diary**

We will contact you to ask that you begin recording your hypoglycaemic events over the next two weeks in your symptom diary.

**Week 15: Home visit and start of second exercise program**

If you began the study with the low-intensity exercise program, you will now change over to the high-intensity program, and vice-versa. The visiting researcher will help you become familiar with your new program. You will also be asked to complete two questionnaires on hypoglycaemia awareness. We will collect your symptom diary, and provide you with a new symptom diary and supply of glucose sensors.

**Week 17: Phone call to commence record of symptom diary**

We will contact you to ask that you begin recording your hypoglycaemic events over the next two weeks in your symptom diary.

**Week 19: Face-to-face hospital or home visit, and end of second exercise program**

You will be asked to complete questionnaires on hypoglycaemia awareness and on your enjoyment of physical activity, and return your hypoglycaemia symptom diary. If you had just completed the high-intensity exercise program, you will be asked to complete a short semi-structured interview with one of our research team, which we will record with your permission so we can see how achievable the exercise program was. Lastly, we will arrange to collect the exercise bike, activity-monitoring watch, and any remaining glucose sensors.

**Is there likely to be a benefit to me?**

There may be no benefit to you, but if the exercise programs are practical and show that they may improve glucose control and reduce hypoglycaemia, we will run larger studies to see which exercise intensity may be used as a treatment approach in people with T1D.

**Is there likely to be a benefit to other people in the future?**

Guidelines for diabetes encourage people with T1D to have a healthier lifestyle by increasing their exercise levels. People with T1D could benefit in the long run if these home-based low and high intensity exercise programs can be incorporated into your daily routine.

**What are the possible risks and/or side effects?**

There is a risk of having low blood glucose levels during and after exercise. You will be required to wear a glucose sensor which will alert you when your blood glucose levels are falling, and so you can prevent hypoglycaemia by eating carbohydrates when you get the alert.

**What are the possible discomforts and/or inconveniences?**

You may experience a skin reaction or infection where the glucose sensor is inserted ﴾reddened skin, itching﴿, but this is rare. Sensors are treated with antibacterial substances and you will be encouraged to clean your skin prior to insertion to minimise this risk.

**Where is your information kept?**

All information that can identify you by name will be treated as confidential and stored safely, so that only the research team can see that information. Electronic study data will be saved on the secure Telethon Kids Institute RedCap server and stored in a password protected database at Perth Children’s Hospital. Garmin activity watch and Dexcom glucose monitoring data will be saved on their company’s online platforms before being transferred to a password protected database at Perth Children’s Hospital. No personal information will be used in this process.

**What about my privacy?**

Your data will be coded and stored on secure PCH computers. Only the investigators and the research team will be able to link your results to you.

All data published and/or presented from this study will not identify you by name.

**Who has approved the study?**

This study has been approved by the Child and Adolescent Health Service Human Research Ethics Committee. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**Who to contact for more information about this study:**

If you would like any more information about this study, please contact

Name: **Dr Mary Abraham**

Telephone contact: **08 6456 5027**
Email: Mary.Abraham@health.wa.gov.au

Name: **Dr** **Wayne Soon**

Telephone contact: **08 6456 4532**
Email: Wayne.Soon@health.wa.gov.au

**Who to contact if you have any concerns about the organisation or running of the study?**

If you have any concerns or complaints about this study, you or your parent can contact the Executive Director of Medical Services at PCH (Telephone No: (08 64562222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

**What to do next if you would like to take part in this research:**

If you would like to take part in this research study, please contact Dr Mary Abraham to make an appointment.

**THANK YOU FOR YOUR TIME**



**FORM OF CONSENT**

**Perth Children’s Hospital**

**PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND SUBJECTS CAN WITHDRAW AT ANY TIME WITH NO IMPACT ON CURRENT OR FUTURE CARE.**

I .................................................................................................... have read

 Given Names Surname

the information explaining the study entitled

**The effect of different exercise intensities in improving glycaemic control in individuals with impaired hypoglycaemia awareness**

I have read and understood the information given to me. Any questions I have asked have been answered to my satisfaction.

I agree to participate in the study.

I understand that I may withdraw from the study at any stage.

I agree that research data gathered from the results of this study may be published, provided that I am not identified by name.

Dated ................................. day of ............................................................ 20 ..........

Participant’s Signature .........................................................................

I, ........................................................................... have explained the above to the

 (Researcher’s full name)

signatories who stated that he/she understood the same.

Signature ...............................................................................................

Date………………………….